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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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09/843,181

04/26/2001

Chris Sikorski

CER-298

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07/02/2002

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EXAMINER

WHITE, EVERETT NMN

ART UNIT

PAPER NUMBER

1623

DATE MAILED: 07/02/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/843,181

Applicant(s)

SIKORSKI ET AL.

Examiner

EVERETT WHITE

Art Unit

1623

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-18 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-18 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on ____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) ____.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). ____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

DETAILED ACTION

Duplicate Claims, Warning

1. Applicant is advised that should Claims 2-4 and 6 be found allowable, Claims 8-11 will be objected to under 37 CFR 1.75 as being a substantial duplicate thereof. When two claims in an application are duplicates or else are so close in content that they both cover the same thing, despite a slight difference in wording, it is proper after allowing one claim to object to the other as being a substantial duplicate of the allowed claim. See MPEP § 706.03(k).

Claim Rejections - 35 USC § 112

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:
The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.
3. Claims 1, 3-6 and 9-11 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The term "modified" in Claim 1, line 1 is a relative term, which renders the claim indefinite. The term "modified" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. Claims 3-6 and 9-11 are also rejected since these claims also do not clarify the term "modified" in Claim 1.

In Claim 6, line 1, the term "method" lacks clear antecedent basis by depending from Claim 1 since Claim 1 set forth the term "process". The term "method" in Claim 6 should be changed to --process-- in order to overcome this rejection.

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the

invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

5. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

6. Claims 1-5 are rejected under 35 U.S.C. 103(a) as being unpatentable over Shah et al (US Patent No. 6,153,746) in view of Walsh (US Patent No. 5,980,971).

Applicants claim a process for making a dried modified cyclodextrin product with improved dusting and aqueous dissolution properties comprising drying an aqueous solution of modified cyclodextrin on a double-drum dryer; and recovering a dried modified cyclodextrin product with improved dusting and aqueous dissolution properties.

The Shah et al patent discloses sulfoalkyl ether cyclodextrins that are suitable for use as clathrating agents with drugs to provide complexes, which are useful in parenteral and other pharmaceutical formulation. The Shah et al patent provides a solution of sulfoalkyl ether cyclodextrin that can be isolated by a suitable drying technique that may be selected as vacuum drum drying (see column 3, lines 23-26). The sulfoalkyl ether cyclodextrin embraces the modified cyclodextrin product of the instant claims. See column 1, line 51 of the Shah et al patent whereby hydroxypropyl- β -

cyclodextrin is disclosed as a well known cyclodextrin for forming inclusion complexes with hydrophobic molecules, which embraces the hydroxypropylated beta-cyclodextrin set forth in instant Claim 2. The instant claims differ from the Shah et al patent by claiming that the dryer thereof is a double-drum dryer. The Walsh patent shows that the interchangeability of single and double drum dryers is well known in the art. See column 6, first paragraph of the Walsh patent whereby drying apparatuses are disclosed that include single and double drum dryers. The paragraph further discloses the drum dryers being heated by steam from 10 to 150 pounds of pressure per square inch, which embraces the subject matter of instant Claims 3 and 4. The paragraph further explains that the thickness of the product can be varied by changing the settings of the drum dryer gap between the rolls, whereby a preferred product is a material of 0.0001 to 0.25 inches in thickness, which covers the particle size range set forth in instant Claim 5. Accordingly, it would have been obvious to one of ordinary skill in the art at the time the invention was made to substitute the drum drying apparatus used to recover the modified cyclodextrin product of the Shah et al patent with a double drum dryer in view of the recognition in the art, as evidenced by the Walsh patent, that use of double drum dryer is an effective and preferred apparatus for the recovery of dried products.

7. Claims 6-11 are rejected under 35 U.S.C. 103(a) as being unpatentable over the Shah et al and Walsh patents as applied to Claims 1-5 above, and further in view of Giacobello (US Patent No. 4,127,944).

Applicants claim a process for making a dried agglomerated modified cyclodextrin product comprising drying an aqueous solution of modified cyclodextrin on a double-drum dryer; and recovering a dried modified cyclodextrin product with improved dusting and aqueous dissolution properties. This claimed subject matter set forth in instant Claims 6-11 is identical to the subject matter of instant Claims 1-5, except for the term "agglomerated" used to describe the modified cyclodextrin product.

The information disclosed in the Shah et al and Walsh patents as set forth above to describe a process for making a modified cyclodextrin product that comprises drying the aqueous solution thereof on a double drum dryer is brought forth for the instant

rejection. Neither the Shah et al patent or the Walsh patent discloses that the modified cyclodextrin is agglomerated. However, the Giacobello patent teaches that the use of a drum dryer to improve the agglomeration of a dried product is well known in the art. See the text at column 10, 3rd paragraph of the Giacobello patent whereby a variation in the drying method is disclosed whereby a drum dryer can be enclosed in a vacuum chamber where the actual drying is carried out under reduced pressures. Giacobello discloses "that such variation will ordinarily hasten the drying process and in some instances lead to still further improved agglomeration of the dried product with consequent production of less fines while maintaining high absorbent properties". It is noted that the Shah patent does disclose the use of "vacuum drum drying" to produce the modified cyclodextrin product thereof (see column 3, line 26 of the Shah patent), which suggests an agglomerated product in view of the teachings of the Giacobello patent. Accordingly, it would have been obvious to one of ordinary skill in the art at the time the invention was made to substitute the drum drying process conditions for preparing a dried modified cyclodextrin using the combination of the Shah et al and Walsh patents with a process condition whereby the drum dryer is enclosed in a vacuum chamber in view of the recognition in the art, as evidenced by the Giacobello patent, that such process condition allows for further improvement of agglomeration of dry products with production of less fines while maintaining high absorbent properties.

8. Claims 12-18 are rejected under 35 U.S.C. 103(a) as being unpatentable over the Majid et al (US Patent No. 5,070,081) in view of Shah et al (US Patent No. 6,153,746).

Applicants claim a dried agglomerated modified cyclodextrin product having about 90% or more by weight of said product with a particle size of less than or equal to about 200 microns and about 50% or more by weight of said product with a particle size of greater than or equal to about 20 microns.

The Majid et al patent shows that preparation of agglomerated cyclodextrin products are well known in the art (see abstract). See column 3, 4th paragraph of the Majid et al patent whereby it is explained that the size of the agglomerates can be

varied by controlling the amount of water added and to a lesser degree the agitation. This passage embraces the particle size limitation set forth in the instant claims. The Majid et al patent further discloses that the starting cyclodextrin can be any of the alpha, beta or gamma forms known in the art (see column 2, lines 63-64), which covers the beta-cyclodextrin limitation set forth in instant Claim 15. With regard to the process limitations of the claimed product that is set forth in instant Claims 14 and 16 -18, applicants are reminded that process limitations cannot impart patentability to a product which is not patentably distinguished over the prior art. The instantly claimed invention differs from the Majid et al patent by claiming that the cyclodextrin product is a modified cyclodextrin.

The Shah et al patent shows that modified cyclodextrin product, such as hydroxypropyl- β -cyclodextrin (see column 1, line 51) and sulfoalkyl ether cyclodextrin (see column 2, line 59), are well known in the art. The Shah et al patent further shows that the modified cyclodextrin products are suitable for use as clathrating agents with drugs to provide complexes, which are useful in parenteral and other pharmaceutical formulations.

The Majid et al patent also discloses utility of the cyclodextrin products thereof for preparation of pharmaceuticals. One would be motivated to combine the Shah et al patent and the Majid et al patent in a rejection of the claims in view of the similar utility of the cyclodextrin products in both patents.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to substitute the cyclodextrin product in the Majid et al patent, before being subjected to the agglomeration procedure, with a modified cyclodextrin product in view of the recognition in the art, as evidenced by the Shah et al patent, that the modified cyclodextrin products are effective as clathrating agents with drugs to provide complexes that are useful in pharmaceutical formulations.

9. All the pending claims are rejected.

Examiner's Telephone Number, Fax Number, and Other Information

10. For 24 hour access to patent application information 7 days per week, or for filing applications, please visit our website at www.uspto.gov and click on the button "Patent Electronic Business Center" for more information.

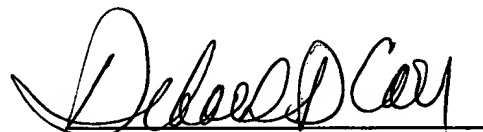
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Everett White whose telephone number is (703) 308-4621. The examiner can normally be reached on Monday-Friday from 9:30 AM to 6:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Johann R. Richter, can be reached on (703) 308-4532. The fax phone number for this Group is (703) 308-4556.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-1235.



E. White



DEBORAH CARR
PRIMARY EXAMINER
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